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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,866	07/22/2003	Dennis M. Brown	67716-5012US	7980

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EXAMINER

HENLEY III, RAYMOND J

ART UNIT	PAPER NUMBER
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1614

MAIL DATE	DELIVERY MODE
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07/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/625,866

Applicant(s)

BROWN, DENNIS M.

Examiner

Raymond J. Henley III

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 June 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1614

CLAIMS 1-15 ARE PRESENTED FOR EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's submission filed on June 6, 2006 has been entered. Accordingly, claims 1, 6 and 7 have been amended.

In light of the amendments, the claim objection and rejection under 35 U.S.C. § 112, first[†] paragraph, as set forth in the previous Office action dated May 5, 2006, have been overcome and thus are hereby withdrawn.

Also withdrawn is the provisional, obviousness-type double patenting rejection set forth in the previous Office action, *Id.*, over the claims of co-pending U.S. Application Serial No. 10/617,927, (the '927 application). The '927 application has been refiled as U.S.S.N. 11/497,739, (the '739 application). The claims of the '739 application define a "sealed container" having contained therein a tartrate salt of homoharringtonine. Accordingly, the subject matter defined in the claims of the '739 application is patentably distinct from the presently claimed methods of inhibiting angiogenesis and of inhibiting the onset or progression of an angiogenic disease.

Claim Rejections - 35 USC § 103

I Claims 1, 4-9 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell et al. (U.S. Patent No. 3,793,454) in view of D'Amato (U.S. Patent No. 5,712,291), Kawai et al. (Cancer Letters, 171 (2001) 201-207) and Powell II, (Journal of Pharmaceutical Sciences article), each of record, for the reasons of record as set forth in the previous Office action, *Id.*, as applied to claims 1, 4-6 and 15, which reasons are here are here incorporated by reference.

Applicant's remarks have been carefully considered, but fail to persuade the Examiner of error in maintaining the rejection.

In particular, whether or not one of ordinary skill in the art would interpret Example 3 of Powell as calling for the implantation of leukemia L1210 or P388 cells into the peritoneal cavity, and thus not forming tumors that require vascularization, is not probative of non-obviousness. The broader, instructive disclosure of Powell is that the actives disclosed can be used for the treatment of leukemia, a disease characterized in art as an angiogenic disease. Even assuming, *arguendo*, that the animal model employed by the patentees does not show an instance of angiogenesis, such would not diminish the instructive effect of the reference on one of ordinary skill in the art who would have accepted the broad teachings of the patentee to use the actives disclosed thereby to treat leukemia. One of ordinary skill in the art would have recognized the clinical usefulness of the invention of Powell, including in instances of non-experimentally induced leukemia, a disease known to be one of angiogenesis.

Art Unit: 1614

Claims 7-9, 13 and 14 are newly included in this rejection. The claims define a method of inhibiting the onset or progression of an angiogenic disease in a host. To the extent that the references have been found to "treat" such a disease, these claims are deemed properly included.

Claim 1 has been amended to include the requirement that the method is one "consisting essentially of" contacting the host with the claimed actives. Insofar as the requirement of the administration of an additional active or an additional method step in the prior art, as compared to the presently claimed subject matter, is not an issue, this claim amendment is not deemed to alter the Examiner's reasons for maintaining the present rejection.

The claims have also been amended by inserting the express statement that angiogenesis is inhibited. While, as previously stated by the Examiner, the prior art is silent with respect to the inhibition of angiogenesis, the claims are nevertheless believed to remain properly rejected because for the reasons already of record, angiogenesis and the claimed diseases/disorders have been associated. Thus, inherent in the prior art is what Applicant is claiming. It should be noted that for inherency, an express disclosure is not required.

Accordingly, for the above reasons, the claims are deemed properly rejected.

II Claims 1-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chinery et al. (U.S. Patent Application Publication No. 2001/0049349) in view of D'Amato (U.S. Patent No. 5,712,291), Cecil's Textbook of Medicine (pp. 1060-1074), O'Dwyer et al., (Journal of Clinical Oncology article), Medford (U.S. Patent No. 5,380,747) and Powell II, (Journal of Pharmaceutical Sciences), each of record, for the reasons of record as set forth in the previous Office action, *Id.*, as applied to claims 1-6 and 15, which reasons are here incorporated by reference.

Art Unit: 1614

Applicant's remarks have been carefully considered, but fail to persuade the Examiner of error in maintaining the rejection.

Claims 7-14 are newly included in this rejection. The claims define a method of inhibiting the onset or progression of an angiogenic disease in a host. To the extent that the references have been found to "treat" such a disease, these claims are deemed properly included.

Claim 1 has been amended to include the requirement that the method is one "consisting essentially of" contacting the host with the claimed actives. The prior art teaches the requisite administration of not only the presently claimed actives, but a non-claimed active, i.e., an antioxidant. Contrary to the opinion expressed by Applicant, the step of administering an antioxidant is believed to be allowed by the present claims because it is not seen that the administration of such would affect the "basic and novel" characteristics of the claimed subject matter, (see MPEP § 2111.03). In particular, whether an antioxidant is administered or not, the present method would be effective for the inhibition of angiogenesis.

Also, the effect of the "consisting essentially of" limitation, lying in between "comprising" and "consisting of" with respect to what it allows the claim to include, is somewhat confounding by the further requirement in the dependent claims, (i.e., claim 6), which allows the claims to include the step of contacting which "comprises the administration" of the claim defined actives.

The claims have also been amended by inserting the express statement that angiogenesis is inhibited. While, as previously stated by the Examiner, the prior art is silent with respect to the inhibition of angiogenesis, the claims are nevertheless believed to remain properly rejected because for the reasons already of record, angiogenesis and the claimed diseases/disorders have

Art Unit: 1614

been associated. Thus, inherent in the prior art is what Applicant is claiming. It should be noted that for inherency, an express disclosure is not required.

Accordingly, for the above reasons, the claims are deemed properly rejected.

Double Patenting

Provisional Obviousness-Type

II Claims 1-15 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over either of (i) claims 1, 17 and 19-24 of co-pending Application No. 10/769,638, or (ii) claims 7, 8 and 13-15 of co-pending application Serial No. 10/631,106 for the reasons of record as set forth in the previous Office action, *Id.*, which reasons are here incorporated by reference.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's remarks at page 8 of the amendment have been carefully considered, but fail to persuade the Examiner of error in maintaining these rejections.

In particular, while the claims of co-pending applications require the administration of an active not recited in the present claims, while present claim 1 has been amended to recite that the method is one "consisting essentially of" administering one of the actives of the co-pending claims, it has not been established that the administration of the active not claimed here would affect the "basic and novel" characteristics of the presently claimed method, i.e., that the administration of additional active of the co-pending claims would not allow for the presently claimed method (see MPEP § 2111.03).

Accordingly, for the above reasons, the claims are deemed properly rejected.


Art Unit: 1614

None of the claims are currently in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond J. Henley III whose telephone number is 571-272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Raymond J Henley III
Primary Examiner
Art Unit 1614

June 28, 2007